



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,896	10/16/2006	Ferdinand Hermann Bahlmann	P/2107-297	4965
2352	7590	04/20/2011	EXAMINER	
OSTROLENK FABER GERB & SOFFEN			DEBERRY, REGINA M	
1180 AVENUE OF THE AMERICAS				
NEW YORK, NY 100368403			ART UNIT	PAPER NUMBER
			1647	
			MAIL DATE	DELIVERY MODE
			04/20/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,896	BAHLMANN ET AL.	
	Examiner	Art Unit	
	REGINA M. DEBERRY	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 February 2011.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 4-6, 10, 15, 19, 32, 39, 40, 45, 49, 52-54 and 57-65 is/are pending in the application.
- 4a) Of the above claim(s) 4-6, 10, 15, 19, 32, 39, 40, 45, 49, 52, 53 and 58-64 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 54, 57 and 65 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/14/10</u> . | 6) <input type="checkbox"/> Other: _____ . |

Status of Application, Amendments and/or Claims

The amendment and Applicant's arguments, filed 04 February 2011, have been entered in full. Claims 1-3, 7-9, 11-14, 16-18, 20-31, 33-38, 41-44, 46-48, 50, 51, 55 and 56 are canceled. Claims 4-6, 10, 15, 19, 32, 39, 40, 45, 49, 52, 53, 58-64 are withdrawn from consideration as being drawn to a non-elected invention. Claims 54 and 57 are amended. New claim 65 was added. Claims 54, 57 and 65 are under examination.

Information Disclosure Statement

The information disclosure statement(s) (IDS) (filed 14 October 2010) was received and complies with the provisions of 37 CFR §§1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits. It is noted that lined references which state "considered do not print" have been considered by the Examiner, but will not be printed on the face of the patent issuing from this application because they are not true publications.

Withdrawn Objections And/Or Rejections

The rejection to claims 54 and 57 under 35 U.S.C. 112, second paragraph, as set forth at page 19 of the previous Office Action (30 September 2010), is *withdrawn* in view of the amendment (04 February 2011).

Claim Rejections-35 USC § 112, First Paragraph, Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1647

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 54, 57 and (new claim 65) remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

“a method for treating acute or chronic renal failure in a human or animal patient ...comprising a subpolycythemic dosage of at least one of **wild-type erythropoietin** or Aranesp...”(claim 54)

“a method for treating acute or chronic renal failure in a human or animal patient ...comprising from 0.001 to 35 IU/kg of body weight per week of **wild-type erythropoietin** or 0.000005 to 0.175 ug/kg of body weight per week of Aranesp...”(claim 65)

does not reasonably provide enablement for:

“a method for treating acute or chronic renal failure in a human or animal patient ...comprising a subpolycythemic dosage of at least one of **erythropoietin** or Aranesp...”(claim 54)

“a method for treating acute or chronic renal failure in a human or animal patient ...comprising from 0.001 to 35 IU/kg of body weight per week of **erythropoietin** or 0.000005 to 0.175 ug/kg of body weight per week of Aranesp...”(claim 65)

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The basis for this rejection is set forth at pages 2-6 of the previous Office Action (30 September 2010).

Applicant submits that they do not agree with the Examiner but in order to advance the progress of the application, claim 54 has been amended in response to the enablement rejection.

Applicant's arguments have been fully considered but are not found persuasive. The Examiner has noticed that the term "erythropoietin" encompasses not only wild-type forms of EPO, but its derivatives, analogs, modifications, muteins, mutants or others as long as they exhibit the biological effects of wild-type erythropoietin. This teaching is cited on page 21, last paragraph of the instant specification. The instant claims are drawn to a genus of "molecules" based entirely on function (i.e. biological effects of wild-type erythropoietin). Furthermore, wild-type erythropoietin has many biological effects. The skilled artisan would accordingly have no resort save trial-and-error experimentation to determine which of the astronomically large number of possible structural variants had the functional properties of the claimed proteins. Such experimentation would be undue for one skilled in this art. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Claim Rejections-35 USC § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 54 and 57 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jungers et al., Nephrology Dialysis Transplantation 16:307-312 (2001) in view of Stehouwer et al., Nederlands tijdschrift voor geneeskunde. Abstract in English. Vol. 141/No. 34:1649-53 (Aug 23 1997). The basis for this rejection is set forth at pages 6-19 of the previous Office Action (30 September 2010).

Applicant argues that Jungers et al. relates to the treatment of anemia, which treatment is shown in the reference to lead to an increase in hemoglobin (Hb) values. Applicant argues that this is in contrast to the instant method which aims to avoid any increase in the hematocrit values. Applicant argues that the Examiner takes the position that the dose of 54.3 units/kg per week of EPO (as disclosed in Jungers), is a subpolycythemic dose as defined by the instant specification. Applicant argues that pages 44-47 of the instant specification teach the definition of a subpolycythemic dose as a dose that does not lead to an increase in a subject's hematocrit. Applicant argues that the numerical values given in the present application (1 to 90 IU/kg of body weight

per week) merely span the potential relevant dosage area in which a dose, specifically designed to take into account the body's physiology, the severity of the disorder, and renal function, may (might not) be subpolycythemic. Applicant argues that a specific dose "x" (e.g., 60 IU/kg body weight per week) falling within the range of 1 to 90 IU/kg body weight per week taught in Applicants' specification may, under particular circumstances in a particular patient, function as a subpolycythemic dose, whereas, in a different patient and/or under different conditions such a dose may not be a subpolycythemic dose but would instead be a polycythemic dose. Applicant directs the Examiner's attention to pages 44-46 of the present specification which states that actual dosages are chosen according to the severity of the disorder and depending on the renal function but wherein, in any event, the dosage administered must be a subpolycythemic dose. Applicant argues that the final arbiter is not the specific amount of the dose, but rather, the fact that the dose does not raise the subject's hematocrit. Applicant argues that the criticality in determining whether a dosage is subpolycythemic lies not in maintaining a dosage of between 1-90 IU/kg body weight per week (which may encompass dosages that are polycythemic as well as dosages that are subpolycythemic), but rather in the administration of a dosage that does not raise the subject's hematocrit when taking into account the particular patient and their particular condition. Applicant argues that the Stehouwer et al. reference in no way discloses or suggests the claimed subpolycythemic dosage of erythropoietin or Aranesp. Lastly, Applicant contends that new claim 65 is also believed to be distinguishable over the cited combination. The claim recites that the dosage ranges from 0.001 to 35 IU/kg of

Art Unit: 1647

body weight per week of erythropoietin or 0.000005 to 0.175 ug/kg of body weight per week of Aranesp. Applicant maintains that the numerical dosage is nowhere taught or even suggested in either Jungers et al. or Stehouwer et al.

Applicant's arguments have been fully considered but are not found persuasive for the following reasons. It appears that Applicant is confusing *hematocrit* with *hemoglobin*. Applicant argues that Jungers' treatment using EPO lead to an increase in *hemoglobin (Hb) values*. However, the specification defines subpolycythemic doses as doses which do not lead to an increase of **hematocrit**. This was stated in the previous Office Action (9/30/10, pages 8-9).

Because instant claims 54 and 57 do not recite specific dosage amounts that are subpolycythemic, the Examiner must go to the specification to discern a definition for subpolycythemic dosages. The specification states, "**all of the foregoing doses provided according to the invention**, for example of 1-2000 units (IU)/week per patient, especially, for example, of 550-2000 IU/week per patient, **are subpolycythemic doses, or in other words doses that do not lead to an increase of the hematocrit..**"(bottom of page 44). "The subpolycythemic doses provide according to the invention correspond to weekly doses of about 1-90 IU of EPO/kg of body weight (top of page 45). "**All of the foregoing doses provided according to the invention**, for example of 0.01-90 units (IU)/kg/week per patient, especially, for example, of 0.01-50 IU/kg/week per patient, **are subpolycythemic doses, or in other words doses that do not lead to an increase of the hematocrit..**"(bottom of page 46-top of page 47). Instant claims 56 and 57 encompass the therapeutic amounts as taught

by the instant specification as being subpolycythemic doses. Jungers et al. teach the administration of 54.3 +- 16.5 IU/kg/week of EPO to chronic renal failure (CRF) patients. Thus, by definition of the instant specification, Jungers et al. administers a subpolycythemic dose. The Stehouwer reference was used to teach that microalbuminuria, hypertension, endothelial dysfunction and an increased risk of left ventricular hypertrophy are aspects in CRF patients.

Lastly, Applicant's arguments that subpolycythemic dosages in a particular circumstance or in a particular patient population, functions as a subpolycythemic dose, whereas in a different patient and/or under different conditions such a dose may not be a subpolycythemic dose but would instead be a polycythemic dose are not found persuasive. Limitations such as circumstances, body physiology, severity of disorder, etc are not cited in the instant claims. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained. Applicant appears to be arguing that their claims are not enabled due to unpredictability and lack of guidance concerning dosage. In view of applicant's arguments the specification could be considered misleading in its disclosure.

NEW CLAIM REJECTION/OBJECTION

Claim Rejections-35 USC § 112, First Paragraph, Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 54, 57 and 65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is reminded of the revision to the Written Description Training Materials, created on March 25, 2008 to supersede and replace the 1999 training materials. The Examiner's arguments are based on Examples from the Revision to the Written Description Training Materials, created on March 25, 2008, to supersede and replace the 1999 training materials. For more information, please see www.uspto.gov/web/menu/written.pdf.

The claimed subject matter is not supported by an adequate written description. The instant claims recite the limitation, "erythropoietin". The instant specification teaches that the term "erythropoietin" encompasses not only wild-type forms of EPO, but its derivatives, analogs, modifications, muteins, mutants or others as long as they exhibit the biological effects of wild-type erythropoietin (page 21, last paragraph). The scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. *Furthermore, the teaching, ".or others as long as they exhibit the biological effects of wild-type erythropoietin" can encompass biomolecules such as lipids, antibodies, nucleic acids, chemical analogs, non-EPO proteins, etc.* No structural characteristics are provided for "or others". The number of structures encompassed by the claims may be vast or conversely there may be no structures that possess the

claimed function. The specification does not describe any correlation between the sequences/structure of compositions, nucleic acids, antibodies, chemical analogs, small molecules, all EPO variants and the biological effects of wild-type EPO. There is no information regarding what structural features would likely be associated with such activity. There is no teaching in the specification regarding how the structures can be varied while retaining such activity. There is no structural element correlative with any type of function. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus, and thus, that the Applicant was not in possession of the claimed genus as recited in the instant claims.

Claim Rejections-35 USC § 112, First Paragraph, Written Description (New Matter)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 65 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The specification as originally filed does not provide support for the invention as now claimed:

"0.001 to 35 IU/kg of body weight per week erythropoietin"

"0.000005 to 0.175 ug/kg of body weight per week Aranesp"

Applicant's amendment, filed 04 February 2011, asserts that no new matter has been added. Applicant states that the new claim is supported by the originally filed application and thus do not raise any issues of new matter.

The Examiner cannot locate the wording or connotation of the instant claims.

The Examiner has found the following teachings:

"EPO doses of 0.001 to 90 IU/kg/week" and "0.05 to 35 IU/kg/week" (page 46)
"weekly dose of Aranesp of 0.000005 to 0.45 ug/kg of body weight" and "0.00025 to 0.175 ug/kg of body weight" (page 47).

The Examiner cannot find the range "0.001 to 35 IU/kg of body weight per week erythropoietin" or "0.000005 to 0.175 ug/kg of body weight per week Aranesp"

The specification as filed does not provide a written description or set forth the metes and bounds of this "limitations". The instant claims now recite limitations which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as-filed.

Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to provide specific written support for the "limitations" indicated above or rely upon the limitations set forth in the specification as filed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 54, 57 and 65 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 13 of copending Application No. 12/759,321 in view of Stehouwer et al., (Reference of record; Nederlands tijdschrift voor geneeskunde. Abstract in English. Vol. 141/No. 34:1649-53; Aug 23 1997).

The instant claims are drawn to a method for treating acute or chronic renal failure in a human or animal patient exhibiting a) at least one dysfunction of endothelial progenitor cells, b) hypertension and c) at least one end-organ damage, wherein the at least one end-organ damage is selected from the group consisting of left ventricular hypertrophy, microalbuminuria, proteinuria and a glomerular filtration rate of 30 to 80 ml/min, said method comprising administering to said patient a pharmaceutical composition comprising a subpolycythemic dosage of at least one of erythropoietin (or 1-45 IU/kg of body weight per week or 0.001 to 35 IU/kg of body weight per week) or Aranesp (or 0.000005 to 0.175 ug/kg of body weight per week), wherein the acute or chronic renal failure is thereby treated in said human or animal patient by diminution or slowing of the damage to kidney tissue.

The claims of copending Application No. 12/759,321 are drawn to a method for the treatment of chronic renal failure, said method comprising administering a pharmaceutical composition comprising a subpolycythemic erythropoietin dose corresponding to a weekly dose of 1 to 90 international units (IU) EPO/kg body weight to a subject in need of said treatment of diminishing the progression of said chronic renal failure.

Stehouwer et al. teach that microalbuminuria, hypertension, endothelial dysfunction and an increased risk of left ventricular hypertrophy are aspects in CRF patients.

The weekly dosages of EPO treatment for chronic renal failure (CRF) overlap in scope between the instant claims and the claims of copending Application No. 12/759,321. Further, Stehouwer et al. teach that microalbuminuria, hypertension, endothelial dysfunction and an increased risk of left ventricular hypertrophy are aspects in CRF patients. Thus, it would have been obvious to modify the dosages because routine optimization is deemed merely a matter of judicious selection and routine optimizations, which is well within the purview of the skilled artisan. This is a provisional obviousness-type double patenting rejection.

Claim Rejections-35 USC § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson, US Patent 7,078,376 B1 in view of Stehouwer et al. (Reference of record; Nederlands tijdschrift voor geneeskunde. Abstract in English. Vol. 141/No. 34:1649-53; Aug 23 1997).

Thompson teaches therapeutic uses of Epoetin omega (abstract and column 1, lines 1-15). Thompson teaches the use of Epoetin Omega to treat end stage renal disease (column 13, lines 10-25 and column 22, lines 40-58). Thompson teaches a lower occurrence of hypertension in anemic dialysis patients using Epoetin omega (column 13, lines 40-67). Thompson teaches administering Epoetin omega at a dose of about 10 to about 100 IU/kg per week (column 19, lines 35-53).

Stehouwer et al. teach that microalbuminuria, hypertension, endothelial dysfunction and an increased risk of left ventricular hypertrophy are aspects in CRF patients.

It would have been obvious at the time the invention was made to modify a method of treating end stage renal disease patients comprising administering 10-100 IU/kg/week of Epoetin omega as taught by Thompson wherein the end stage renal disease patients exhibit microalbuminuria, hypertension, endothelial dysfunction and left ventricular hypertrophy with a reasonable expectation of success. The motivation and expected success is provided by Thompson and Stehouwer et al. Thompson teaches

that when using lower doses of Epoetin omega incidences of elevated blood pressure are decreased compared to other forms of erythropoietin. Hypertension is a condition known to cause damage to the kidneys. Stehouwer et al. teach that microalbuminuria, hypertension, endothelial dysfunction and an increased risk of left ventricular hypertrophy are aspects in CRF patients, which is encompassed by end stage renal disease. It would be obvious to one of skill in the art to employ a pharmaceutical with few adverse side effects.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REGINA M. DEBERRY whose telephone number is (571)272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARIANNE P ALLEN/
Primary Examiner, Art Unit 1647
/R. M. D./
Examiner, Art Unit 1647
4/18/11